

Vitamins and minerals

June 14 is comment deadline on Food and Drug Administration's (FDA) proposed rule which would place limitations on nonprescription or over-the-counter (OTC) vitamin and mineral drug products.

The proposal, based on recommendations of an expert advisory panel, suggests that OTC vitamins and minerals be labeled only for the prevention or treatment of deficiencies. The label would have to make clear that these products should be used only "when the need for such therapy has been determined by a physician."

The panel's report is part of FDA's massive re-evaluation of all nonprescription drugs and is a first step toward development of an FDA standard for the formulation and labeling of nonprescription vitamin and mineral drug products.

Although vitamins and minerals as dietary supplements are the major source of US sales of these products, the panel did not cover this use. Dietary supplements are regulated under FDA's food law.

Among the panel's findings are:

- Deficiencies needing drug treatment with vitamins and minerals occur mainly among special consumer groups such as pregnant women, nursing mothers, people who drink too much alcohol, and people who take prescribed drugs or have diseases that interfere with the body's ability to absorb vitamins and minerals from food.
- Terms such as "stress," "super potency," or "geriatric" should not be allowed as part of a brand name or on labeling for a vitamin-mineral product.
- Labels should not designate a product as "natural," because there is no evidence that "natural" forms of vitamins are better than "synthetic" ones.
- Since consumers cannot easily identify vitamins and mineral deficiencies and since a physician's diagnosis is needed, the symptoms of such deficiencies should not be described on labels of OTC drugs.
- Vitamin E should not be sold by itself as an OTC drug because it has no proven therapeutic value and vitamin E deficiency is virtually unknown. However, it could be added to another product to treat multiple vitamin deficiencies.
- Although some vitamins and minerals are required by the body, they can be dangerous at high levels. For example, large amounts of vitamin A, taken over a long period, can cause irreversible liver and bone damage, and excess amounts of vitamin C can interfere with a common test for sugar in the urine of diabetics.
- Nine vitamins: vitamins C, B¹², A, B⁶, D, folic acid, niacin, riboflavin, and thiamine could be sold as single ingredient OTC drugs to treat deficiencies. Three minerals; calcium, iron and zinc could be sold in the same manner.
- Vitamin K, vitamin E, biotin, choline, and pantothenic acid should be sold only on prescription.

The panel's findings are being issued as a formal proposal to obtain public comment before FDA reaches any decisions. After comments are evaluated, FDA will publish a "tentative final regulation" and ask for further public comment. The agency will then issue a final regulation which will include a monograph or "recipe book" of ingredients that it considers safe and effective for use in OTC vitamin and mineral drug products. The monograph will also specify what claims can be made on product labels.

Details—Federal Register: March 14, page 16126. Send comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857. For more information write or call William Gilbertson, Bureau of Drugs (HFD-510), at above address; telephone 301-443-4960.

Motorcycle helmets

National Highway Traffic Safety Administration (NHTSA) wants as much information as it can get (from individuals, motorcycle manufacturers, and trade associations) on the effect of helmet law repeal on helmet use, injuries and deaths. Deadline for this information is May 8.

Ever since a section of the Highway Traffic Safety Act of 1976, prohibiting Transportation Dept. from requiring states to force persons 18 years of age or older to wear motorcycle helmets, 26 states have either repealed or weakened their helmet use laws. As a result, according to NHTSA, during 1977 there was a 24% increase in motorcycle deaths—reaching a record high of 4,103. And motorcycle deaths increased an estimated 10% during 1978.

Because of concern about the increase in fatalities, Transportation must now conduct a motorcycle helmet study and report the findings to Congress.

To help individuals and others comment on motorcycle helmets, NHTSA is making available a package of information concerning the effect of motorcycle helmet use on head injuries and the effect of the repeal of helmet use laws on the frequency and severity of head injuries. Copies of the package may be obtained by writing to NHTSA, General Service Division (NAD-42), Washington, DC 20590.

Details—Federal Register: March 22, page 17614. Send comments to Docket No. 79-07, Room 5108, Nassif Bldg., National Highway Traffic Safety Administration, Washington, DC 20590. For more information write or call Lewis Buchanan at above address; telephone 202-426-2180.

Asbestos in schools

On March 16 the Environmental Protection Agency (EPA) began a national campaign to help state and local school officials prevent exposing children to hazardous asbestos-containing materials in some schools.

EPA will distribute to each state and to numerous school districts a package of technical guidance materials for use in determining whether school ceilings and walls contain asbestos materials and, if so, what sort of corrective action can be taken. In addition, the agency is now operating (during working hours) a toll-free number to answer questions about the school asbestos problem and fill requests for technical guidance packages. This program is focusing on public school buildings, but EPA will provide information and technical assistance to owners of other types of buildings upon request.

To obtain copies of the package or other EPA publications, write or call John Ritch, Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460; telephone toll-free 800-424-9065. (In Washington, DC, call 554-1404.)

Regional asbestos coordinators are available to give technical assistance on identifying and correcting asbestos problems and may be contacted through the toll-free number listed above.

EPA is setting up this program to help prevent exposure to asbestos since asbestos could cause lung cancer, chronic lung disease or other crippling illnesses 15 to 30 years after exposure. The agency is particularly concerned about the danger to children because they have more time to develop asbestos-related diseases. According to EPA, microscopic fibers released by flaking asbestos in insulation, fireproofing or decorations on school ceilings, walls and fixtures can be inhaled and lodge in the lungs with a time bomb effect. Children, adolescents and school employees spend many hours in school buildings for many years, and the longer they are exposed the greater the danger of developing an asbestos-related disease.

The best scientific opinion is that any exposure to these fibers involves some increase in health risks. The danger to school children depends in large measure on the condition of the asbestos materials and the degree of deterioration or flaking. The more fibers released into the air, the greater the hazard.

At the moment, no one knows how much asbestos-containing materials can be found in our schools and other buildings, although they were commonly applied to ceilings, walls and other building areas between 1946 and 1973. In 1973, EPA banned the use of sprayed material containing more than one percent asbestos for insulation or fireproofing. In 1978, the ban extended to nearly all uses.

The amount of asbestos released into the air depends on a number of conditions, including the activities held in a school. For example, an indoor basketball game may cause vibrations and shake loose asbestos particles from the ceiling. Even a basketball striking an asbestos-coated pipe could release the dangerous fibers.

In some asbestos-containing materials, such as vinyl floor tile, the asbestos fibers are firmly bound together or encased. These materials will not release fibers unless they are cut, ground or sanded. EPA says their main concern is with asbestos materials which are friable (easily crumbled by hand). Such materials are subject to pressure or vibration and can release asbestos fibers which may be swallowed or inhaled. The crumbling problem varies significantly from building to building depending on the material's condition, accessibility and other factors.

Officials faced with an asbestos exposure problem may remedy it in one of 3 ways. They may remove the material entirely, an expensive process that must be done according to strict safety rules. They may seal the asbestos with a sealant, or may place a barrier, such as a suspended ceiling, between it and the children. EPA's guidance material gives school officials the nuts-and-bolts information they need to choose the best course of action.

Details—*Federal Register*: March 23, page 17790.

Energy conservation service

May 25 is deadline for comments on **Energy Dept.**'s proposed regulations which spell out ground rules on the Residential Energy Conservation program established under the 1978 National Energy Act (NEA). (See CONSUMER NEWS: Nov. 1, 1978.)

The regulations propose that large utilities (those with annual sales over 10 billion cubic feet of natural gas or 750

million kilowatt hours of electricity) must offer an energy audit, at the customer's expense, of their residences and information about estimated costs and savings of each solar or energy conservation measure. If requested, the utility company would also arrange for the purchase, installation and financing of these measures.

NEA proposes that the program be operated by the states. Each state would prepare a plan suitable to its own situation and submit it to Energy Dept. for approval. States may decide to allow home heating fuel suppliers to participate in the program also. Large municipal and cooperative utilities, which are required under the NEA to provide the services but which are not included under the state plans, would file plans directly with Energy.

The program would cover approximately 64.7 million homes. It would apply to existing single family houses and to multi-family houses which have no more than 4 units as long as the residents are utility customers and their homes have heating or cooling equipment.

Energy Dept. says, "The consumer will be able to obtain useful information on how to conserve energy in the home, on what conservation and solar measures are cost effective as well as how to arrange for installation and financing."

Consumers could spend as much as \$6.7 billion to effect these conservation measures but would save \$30 billion and 8.2 quads of energy over the lifetime of the improvements, according to Energy Dept.'s preliminary estimates. (A quad is short for 1 quadrillion which equals 1 trillion cubic feet of natural gas, or 293 billion kilowatt hours of electricity, or 172 million barrels of oil. Thus a savings 8.2 quads would be a very large amount.)

Among the energy conserving measures which could be included are; caulking and weatherstripping of doors and windows; furnace efficiency modifications; clock thermostats; ceiling, attic, wall and floor insulation; water heater insulation; storm windows and doors; heat absorbing or heat-reflective glazed windows and door materials; load management devices; duct insulation; pipe insulation; thermal windows and doors; and energy usage display meters.

Renewable resource measures eligible for the program are: solar domestic hot water systems; active solar space heating systems; combined active solar space heating and solar domestic hot water systems; passive solar space heating and cooling systems; wind energy devices; and replacement solar swimming pool heaters.

Also included in the regulations are proposed standards for solar and energy conserving products and materials and installation.

Details—*Federal Register*: March 19, page 16546. Send comments to Margaret Sibley, Office of Conservation and Solar Applications, Energy Dept., 20 Massachusetts Ave., NW, Washington, DC 20545. All comments must be marked on both envelope and document with the designation "Residential Conservation Service," (Docket No. CAS-RM-79-101). For additional information write or call James Tanck at the address above; telephone 202-376-4708.

NOTE: Public hearings yet to be held on energy conservation service are listed in this issue of CONSUMER NEWS on page 4.

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